K091388

Section 5 – Summary of 510(k)

JUL 22 2009

# 510(k) Summary
# for
# MI Fil (GCUC-505)

**Submitter Information:**

GC AMERICA INC.
3737 W. 127th Street
Alsip, IL 60803

Contact Person: Mark Heiss, D.D.S.
Phone: (708) 897-4042
Fax: (708) 897-4031

Date Prepared: May 4, 2009

**Device Name:**

Proprietary Name: MI Fil (GCUC-505)
Classification Name: Tooth Shade Resin Material
Device Classification: Class II, 872.23690
Produce Code: EBF

**Predicate Devices:**

| Company | Device | K Number | Date Cleared |
|---|---|---|---|
| GC America Inc. | GRADIA DIRECT LoFlo | K042348 | 01/30/2003 |
| GC America Inc. | GDLS-200 (Kalore) | K082434 | 11/14/2008 |
| Ivoclar Vivadent, Inc. | TETRIC EVOCERAM | K042819 | 11/09/2004 |

**Description of Device:**

MI Fil (GCUC-505) is a light-cured nano-filled radiopaque composite resin filled in a syringe topped with a needle tip. The device is a flowable composite resin of normal consistency. The material is available in 17 shades.

**Indications for use:**

Restoration of Class I, II, III, IV, V cavities
Restoration of root surface caries
Restorations in deciduous teeth
Filling tunnel shaped cavities
Sealing hypersensitive areas
Liner/base/filling in cavity undercuts
Sealant
Fixing loose teeth
Additions to composite restorations

**Decription of Safety and Substantial Equivalence:**

The applicant device is substantially equivalent to the predicate devices in its intended use. They are all composite resins and are used for the restorations of both anterior and posterior teeth. They are also used as a filling material and sealant.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUL 22 2009

Mark Heiss, D. D. S.
Director of New Business Development and Regulatory Affairs
GC America, Incorporated
3737 West 127th Street
Alsip, Illinois 60803

Re: K091388
Trade/Device Name: MI Fil (GCUC-505)
Regulation Number: 21 CFR 872.3690
Regulation Name: Tooth Shade Resin Material
Regulatory Class: II
Product Code: EBF, EBC, LBH
Dated: May 4, 2009
Received: May 11, 2009

Dear Dr. Heiss:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/cdrh/mdr/ for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Susan Runner, D.D.S., M.A.
Acting Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Section 6 – Indications for Use Statement

**Indications for Use**

**510(k) Number (if known):** K091388

**Device Name:** MI Fil (GCUC-505)

**Indications for Use:**

**Intended use**

Restoration of Class I, II, III, IV, V cavities
Restoration of root surface caries
Restorations in deciduous teeth
Filling tunnel shaped cavities
Sealing hypersensitive areas
Liner/base/filling in cavity undercuts
Sealant
Splinting mobile teeth
Additions to composite restorations

Prescription Use ✓
(Part 21 CFR 801 Subpart D)

AND/OR

Over-The-Counter Use _____
(21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

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Concurrence of CDRH, Office of Device Evaluation (ODE)

Kai Mealy for MSR

(Division Sign-Off)
Division of Anesthesiology, General Hospital
Infection Control, Dental Devices



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